

## REMARKS

The present application is directed to methods comprising administration of compositions comprising mycobacterial cell wall extract for activating the immune system of an animal or enhancing production performance of the animal. In a preferred embodiment, the methods of the present invention involve the administration of compositions comprising mycobacterial cell wall extract from *Mycobacterium phlei*.

In an effort to facilitate prosecution, the claims have been amended and the following remarks are provided in response to the rejections raised in the April 14, 2004 Office Action. No new matter has been added and support for the amendments is found throughout the specification.

### ***Telephone Interview with Examiner Navarro on September 1, 2004***

Applicants wish to thank the Examiner for taking the time to discuss the present application with Dr. John K. McDonald and Ms. Sima S. Kulkarni on September 1, 2004. Applicants appreciate the Examiner's insight and advice.

### ***Double Patenting***

#### **Nonstatutory Double Patenting Rejection over Claims 32-41 and 44-53 of United States Patent No. 5,759,554**

In the April 14, 2004 Office Action, the Examiner rejected Claims 32-41 and 44-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-19 of United States Patent No. 5,759,554 (hereafter '554). The same rejection was maintained in the July 30, 2004 Advisory Action wherein the Examiner further stated that (1) contrary to what Applicants had previously argued, it was not clear 'how' the mycobacterial cell wall extracts were different, and (2) though Applicants had argued that the '554 patent unlike the present application was directed to compositions that *contain* oil, such a limitation does not appear in the claims.

In an effort to facilitate prosecution, Applicants respectfully submit that the mycobacterial cell wall extracts are different because one contains oil and the other does not. In addition, the claims have now been amended to reflect this qualification. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

*Nonstatutory Double Patenting Rejection over Claims 54-69 of United States Patent No. 5,759,554*

In the Advisory Action of July 30, 2004, the Examiner rejected Claims 54-69 for the same reasons as Claims 32-41 and 44-53 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-19 of United States Patent No. 5,759,554 (hereafter '554).

Applicants respectfully maintain, that whereas the '554 claims are directed to methods of "stimulating the immune system of an animal", Claims 54-69 are directed to methods for "enhancing production performance of an animal". Since both endpoints are distinct, applicants respectfully submit that the rejection is inappropriate and withdrawal is requested.

*Nonstatutory Double Patenting Rejection over Claims 32-41 and 44-53 of United States Patent No. 5,632,995*

The Examiner maintained the rejection of Claims 32-41 and 44-53 and newly added claims 54-69 for reasons of record and further stated that applicants' arguments were not found to be persuasive because (1) there is no limitation of the time period for "prior to ovulation" to take place, and (2) though Applicants argued that the treatment animal was a parent animal, no such limitation was recited in the claims.

With respect to Claims 32-41 and 44-53 Applicants respectfully submit that whereas these claims are directed to methods of stimulating the immune system of an animal, the claims of the cited patent are directed to methods of increasing reproductive performance of an animal. As such, since the endpoints of each are distinct, applicants respectfully submit that the rejection is inappropriate and withdrawal is requested.

Application No. 10/031,752  
Preliminary Amendment filed September 14, 2004  
Filed in Connection with Request for Continued Examination  
(and) Reply to Final Office Action dated April 14, 2004

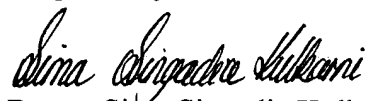
With respect to Claims 54-69 Applicants respectfully maintain that whereas the '995 patent is directed to methods of increasing *reproductive* performance, the present application is directed to *enhancing production* performance. Accordingly, applicants submit that a terminal disclaimer is not appropriate. Reconsideration and withdrawal of this rejection is respectfully requested.

### ***Conclusion***

For at least the above reasons, Applicants respectfully request allowance of Claims 32-69 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is urged to contact the undersigned attorney.

The foregoing is submitted as a full and complete response to the Office Action mailed April 14, 2004 and Advisory Action mailed July 30, 2004. Applicants respectfully submit that the claims are fully enabled, novel and non-obvious over the cited art. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at (404) 745-2463 is respectfully solicited.

Respectfully submitted,



By: Sima Singadia Kulkarni  
Reg. No.: 43,732

KILPATRICK STOCKTON LLP  
1100 Peachtree Street, Suite 2800  
Atlanta, GA 30309-4530  
Phone: (404) 745-2463  
Facsimile: (404) 541-3269  
Attorney Docket No. 18010-0061US (46151-268469)